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EXAMINER

PACKARD, BENJAMIN J

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| ART UNIT | PAPER NUMBER |
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4173

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| MAIL DATE | DELIVERY MODE |
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10/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,400

Applicant(s)

GERSON ET AL.

Examiner

Benjamin J. Packard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 1, 61, 62, 70, 83, 85, 88, 93, 100, 103-106, 172 and 667 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59, 60, 64, 65, 75, 77, 78 and 98-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date (6 sheets).
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,59-62,64,65,67,70,75,77,78,83,85,88,93,98-101,103-106,111,113 and 172.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 59-62, 64, 65, 67, 70, 75, 77, 78, 83, 85, 88, 93, 98, 99-101, 103-106, 111, and 113) in the reply filed on 9/28/2007 is acknowledged. Additionally, applicants elected the species to anticancer agent comprising temozolomide and a BER inhibitor comprising Methoxyamine. The restriction is made FINAL.

Claims 61-62, 66, 70, 83, 85, 88, 93, 100, and 103-106 are withdrawn from further consideration.

Claims 1 and 172 are withdrawn as directed to the nonelected group.

Claims 59, 60, 64, 65, 75, 77, 78, 98, 99 and 100 are now examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 59, 60, 64, 65, 75, 77, 78, and 98-100 rejected under 35 U.S.C. 102(b) as being anticipated by LIU et al (Clin. Cancer Res. 5, 2908-2917, 1999; applicants IDS filed 1/13/2005 sheet 3 item BE).

LIU et al discloses:

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59. A method for potentiating a therapeutic effect of an anticancer agent that induces formation of AP sites, comprising administering a base excision repair (BER) inhibitor, whereby the base excision repair inhibitor potentiates the effect of the anticancer agent.

Methoxyamine (MX), a base excision repair inhibitor (page 2910 column 2 lines 35-36), is disclosed to potentiate the cytotoxic (or therapeutic as shown on page 2916 1st column lines 18-20) effect of temozolomide (TMZ), an anti cancer agent (pg 2910 2nd column lines 5-6) where TMZ creates AP sites (see abstract lines 9-11).

60, 64, 65, 75. See instant claim 59.

77. See page 2914 column 1 lines 6-8 where MX inhibits AP endonuclease.

78. See instant claim 59.

98. The method of claim 59, wherein the amount of anticancer agent is subtherapeutic when administered in the absence of the base excision repair inhibitor.

See page 2912 column 1 lines 4-8 where very low concentration dosages are disclosed, where the drugs in very low concentrations without synergy would be inherently be subtherapeutic.

99 and 100. See page 2914 column 1 lines 6-8 where MX inhibits AP endonuclease.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59, 60, 64, 65, 75, 77, 78, and 98-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,635,677 ('677). Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to methods which have require the delivery of the same components, MX and an anticancer drug that exerts cycotoxicity mediated by oxidative DNA damage, such as TMZ (column 12 lines 61-66). The potentiation of a therapeutic effect of an anticancer agent is inherent in the method of treatment, because the method of '677 comprises the exact same step with the exact same compounds as claimed in the instant application. Neither method is limited to a specific patient population, thus these claims are mutually obvious.

Claims 59, 60, 64, 65, 75, 77, 78, and 98-100 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21

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of U.S. Patent No. 6,465,448 ('448). Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to methods which have require the delivery of the same components, MX and an anticancer drug that exerts cytotoxicity mediated by oxidative DNA damage, such that TMZ will be potentiated by the MX.

Conclusion

No claims allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

18 October 2007
BP


CECILIA TSAING
SUPERVISORY PATENT EXAMINER